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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,270	09/24/2003	Peter A. Altman	212/511	3869

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EXAMINER	
CHENG, JACQUELINE	
ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/671,270	ALTMAN ET AL.	
	Examiner	Art Unit	
	JACQUELINE CHENG	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed November 12, 2009 have been fully considered but they are not persuasive. The examiner respectfully disagrees with the applicant's arguments. Firstly the applicant has misinterpreted the examiner's rejection dated May 12, 2009. The examiner is not suggesting that the stent of Stevens be placed outside the artery to treat the stenotic lesion inside the artery so therefore these arguments are moot. The stent is placed inside the coronary blood vessel and then therapeutic agent is injected peri-adventitially (around the outermost connective tissue covering an organ, vessel or other structure) via needles that protrude outwardly, penetrating through the blood vessel wall.

2. The examiner also respectfully disagrees with the applicant's arguments the Stevens does not mention injecting an agent, this agent in particular being an anti-restenosis agents. Stevens teaches that his invention can be used with any therapeutic agent and in particular states that it can be used to deliver VEGF (abstract) which is an anti-restenosis agent as proven by the applicant as the applicant states their invention delivers VEGF (page 7 line 24 of the applicant's specification) and by Kaul (US 5,961,459) which specifically states that VEGF is an anti-restenosis agent (col. 6 line 41-47). As to the methods of delivery the applicant argues that the uncited passages leading up to the passage cited by the examiner (which was col. 10 line 18-24) teaches that the needles have a coating and that this does not imply injection of an agent. The examiner would like to point out that these passages do not discuss the embodiment with the needles and the coating discussed is applied to the stent, not the needles of the stent. The

examiner believes Stevens is teaching injecting an agent as the passages cited by the examiner states that the needles provide a conduit (using a standard definition of conduit of a tunnel or pipe, i.e. being hollow) for delivery of the agent into the surrounding myocardium, allowing for injection of an agent and in combination with Stevens discloses in a different embodiment of injection of an agent through conduits provided by needles. Although it would appear from fig 15 that the needles do not reach the myocardium, the disclosure of Stevens states that the needles provide delivery of agent into the myocardium, therefore the agent is being delivered to the myocardium.

3. The examiner also respectfully disagrees with the applicant's arguments that Stevens does not disclose combining angioplasty with the injection of an agent. As discussed above Stevens discloses performing angioplasty (mechanically widening the blood vessel by expanding a balloon with a stent on it) in combination with injecting an agent.

4. The examiner also believes that Nash (US 6,709,427) in view of Stegmann (US 2002/0122792) discloses injecitno of anti-restenosis agents. Nash discloses injection of therapeutic agents such as Adenovirus, which is one of the anti-restenosis agents that is injected by the applicant (page 17 line 27 of the applicant's specification).

5. As to the applicant's arguments of the rejection of claim 41, as discussed above the examiner believes that the needles of the stent reach the perivascular space as Stevens states that the needles provide delivery of the agent into the myocardium. Furthermore the embodiment of Stevens shown in figs. 10a and 10b shows a catheter 523 having means for introducing a therapeutic agent 528 into a perivascular space surrounding the blood vessel.

6. Applicant's other arguments have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made along with some of the grounds of rejection made on May 12, 2009.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. **Claims 21, 23, 25, 31, 33, 35** are rejected under 35 U.S.C. 102(e) as being anticipated by Stevens (US 6,152,141). Stevens teaches a method of delivery of therapeutic agents to the heart by injecting an agent directly into the myocardium by inserting a catheter into the coronary artery and piercing the wall of the coronary artery (col. 8 line 37-40, fig. 9) (which would be through the vessel wall into a peri-adventitial layer) to treat intraluminal diseases such as a stenosis (fig. 10b element 102) at a site distal to the segment (fig. 10b). Stevens discloses that the agent can be any type of drug or agent such as VEGF (abstract) which is an anti-restenosis agent (see US 5,961,459 to Kaul which specifically states that VEGF is an anti-restenosis agent in col. 6 line 41-47).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1, 3, 4, 11, 13, 14, 21, 23, 24, 31, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens.

11. **Claims 1, 3, 11, 13, 21, 23, 31, 33:** Stevens teaches as another embodiment of a method of treating stenosis to implant a stent within a coronary artery (performing an angioplasty procedure), the stent having needles that protrude outwards and which upon inflation of a balloon penetrates the coronary artery wall providing a conduit (a tube or pipe, i.e. the needles are hollow) for delivery of a therapeutic agent, which can be any type of drug or agent such as VEGF (abstract) which is an anti-restenosis agent (see US 5,961,459 to Kaul which specifically states that VEGF is an anti-restenosis agent in col. 6 line 41-47), into the surrounding myocardium through the blood vessel wall (col. 10 line 18-24, fig. 15). Stevens does not explicitly disclose how the needles provide a conduit for delivery of a therapeutic agent so it would be obvious to use any well known method such as also disclosed in Stevens. Stevens discloses in regards to fig. 12 a plurality of needles 546 which also upon inflation of a balloon pierce the coronary artery wall providing a conduit for the agent, the agent being injected into the myocardium (col. 9 line 29-26). It would therefore be obvious to use injection as the method of delivering the agent from the stent for the purpose of being able to infuse the desired amount of agent into the myocardium.

12. **Claims 4, 14, 24, 34:** Stevens does not explicitly disclose placing the stent with needles in the coronary vein, however it is obvious to one skilled in the art to place the stent where the occlusion has occurred for the purpose of treating the stenosis. If the occlusion occurred in the coronary vein instead of the coronary artery it would be obvious to place the needle 527 (fig. 10a, 10b) or the stent 548 (fig. 15) in the coronary vein in order to treat the stenosis.

13. Claims 1, 3, 6-8, 10, 11, 13, 16-18, 20, 21, 23, 25-28, 30, 31, 33, 35-38, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens in view of Sahatjian (US 5,843,089).

14. **Claims 1, 3, 6-8, 10, 11, 13, 16-18, 20, 21, 23, 26-28, 30, 31, 33, 36-38, 40:** Stevens teaches as another embodiment of a method of treating stenosis to implant a stent within a coronary artery (performing an angioplasty procedure), the stent having needles that protrude outwards and which upon inflation of a balloon penetrates the coronary artery wall providing a conduit (a tube or pipe, i.e. the needles are hollow) for delivery of a therapeutic agent into the surrounding myocardium through the blood vessel wall (col. 10 line 18-24, fig. 15). Stevens does not explicitly disclose how the needles provide a conduit for delivery of a therapeutic agent so it would be obvious to use any well known method such as also disclosed in Stevens. Stevens discloses in regards to fig. 12 a plurality of needles 546 which also upon inflation of a balloon pierce the coronary artery wall providing a conduit for the agent, the agent being injected into the myocardium (col. 9 line 29-26). It would therefore be obvious to use injection as the method of delivering the agent from the stent for the purpose of being able to infuse the desired amount of agent into the myocardium. Stevens also discloses that the agent being delivered can be any type of drug or agent (col. 2 line 38-48). It would therefore be obvious to use any well known type of

drug or agent such as disclosed by Sahatjian. In the same field of endeavor of using a stent to expand an occluded region of a blood vessel and providing a therapeutic agent to the region Sahatjian discloses the therapeutic agent can be an anti-angiogenic drug, a nucleic acid incorporated into a liposome, or a gene therapy agent such as antisense oligonucleotides and can be incorporated into microspheres to provide a time released formulation (col. 2 line 20-45). It would be obvious to use the therapeutic agents disclosed in Sahatjian in Stevens as Stevens discloses any type of drug can be used as well as for the purpose of preventing restenosis at the stent site as taught by Sahatjian (col. 2 line 20-22).

15. **Claims 21, 23, 25-28, 30, 31, 33, 35-38, 40:** Stevens teaches a method of delivery of therapeutic agents to the heart by injecting an agent directly into the myocardium by inserting a catheter into the coronary artery and piercing the wall of the coronary artery (col. 8 line 37-40, fig. 9) (which would be through the vessel wall into a peri-adventitial layer) to treat intraluminal diseases such as a stenosis (fig. 10b element 102) at a site distal to the segment (fig. 10b). Stevens discloses that the agent can be any type of drug or agent (col. 2 line 38-48). It would therefore be obvious to use any well known type of drug or agent such as disclosed by Sahatjian. In the same field of endeavor of using a stent to expand an occluded region of a blood vessel and providing a therapeutic agent to the region Sahatjian discloses the therapeutic agent can be an anti-angiogenic drug, a nucleic acid incorporated into a liposome, or a gene therapy agent such as antisense oligonucleotides and can be incorporated into microspheres to provide a time released formulation (col. 2 line 20-45). It would be obvious to use the therapeutic agents disclosed in Sahatjian in Stevens as Stevens discloses any type of drug can be used as well as for the purpose of preventing restenosis at the stent site as taught by Sahatjian (col. 2 line 20-22).

16. **Claims 9, 19, 29, and 39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens in view Sahatjian further in view of Levine (US 2002/0019350 A1). Stevens and Sahatjian disclose most of what is claimed including providing agents such as anti-angiogenic agents but fail to disclose how the agents were encapsulated. It would be obvious to deliver the agents, such as an anti-angiogenic agent in any well known carrier vehicles such as micelles as disclosed by Levine (paragraph 0144).

17. **Claim 41 is** rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens further in view of Kunz (US 5,981,568). Stevens does not explicitly disclose a kit comprising the parts of their method. It would be obvious to put the parts needed to perform a method in a kit as well as instructions to perform the method as this is well known in the art to do. For example, Kunz discloses not only a kit to perform a method, but also discloses in particular a kit for inhibiting restenosis comprising a catheter, a dose of therapeutic agent, and instruction means for directing the kit's use. Since the method of Stevens comprises positioning the catheter into the desired location (capable of being the perivasular space) and delivering the dose to where the catheter is placed, it would be obvious that the instructions would state this.

18. **Claims 1, 2, 5-8, 11, 12, 15-18, 21, 22, 25-28, 31, 32, and 35-38** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash in view of Stegmann (US 2002/0122792 A1). Nash discloses a method of delivering agents to a targeted tissue as an adjunctive therapy such as stenting (col. 17 line 19-25) comprising injecting the agent into the myocardium from an

endocardial region (col. 19 line 10-14). Nash does not explicitly disclose from where in the endocardium the agent is injected to so therefore it would be obvious to one skilled in the art to inject the agent from anywhere in the endocardium depending on the region that needs to be treated. If Nash was treating a stenosis in the coronary blood vessel it would be obvious to inject the agent (such as a time released anti-restenosis gene therapy agent, adenovirus, encapsulated in microspheres, col. 30 line 66- col. 31 line 30) proximate the coronary blood vessel as disclosed by Stegmann (paragraph 0015).

Conclusion

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE CHENG whose telephone number is (571)272-5596. The examiner can normally be reached on M-F 10:00-6:30.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline Cheng/
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768